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May 12, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: BASF Corporation's Comments on FDA's Interim Final Rule on the Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act, and on FDA's Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes, Availability -- (Docket No. 2002N-0278)

Dear Sir/Madam:

In response to the Food and Drug Administration's (FDA) notice of the reopening of the comment period for the interim final rule entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period" (Prior Notice), and on "FDA's Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes, Availability", BASF Corporation is respectfully submitting comments. As stated in the Interim Final Rule (IFR), FDA intended to reopen the comment period after affected persons had experience with the systems, timeframes and data elements associated with the registration requirements. The reopening of the comment period, as published in the Federal Register on April 14th, 2004 (*69 Fed. Reg. 19763*), is consistent with that intent and requests comments with regard to specific issues regarding prior notice.

Based in Mt. Olive, New Jersey, BASF Corporation (BC) is a U.S. corporation and the North American affiliate of BASF Aktiengesellschaft (BASF AG), Ludwigshafen, Germany. BC's diverse product mix includes chemicals, coatings, plastic, colorants, and health and nutritional products. Many of these products have applications in food as food additives and are imported from our foreign affiliates or through third parties.

BASF Corporation
3000 Continental Drive - North
Mount Olive, N.J. 07828 -1234
Tel: (800) 526-1072
www.basf.com/usa

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BASF Corporation supports Congress and the FDA in efforts to protect the U.S. food supply from threatened or actual terrorist attacks. We commend FDA on considering Custom and Border Protection's (CBP) Customs-Trade Partnership Against Terrorism (C-TPAT) initiative mechanisms and the Free and Secure Trade (FAST) program timeframes for FDA's prior notice requirements. We have the following comments in response to the questions set forth in your March 2004 *Federal Register* Notices. We also respectfully request additional clarification regarding the inclusion of Secondary Direct Food Additives within the definition of "Food Contact Substances" in the IFR.

I. BASF Corporation's Comments on FDA's Interim Final Rule on the Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act

BASF Corporation's Response Regarding C-TPAT/FAST Questions:

1. Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?

We support the extension of the full expedited processing and information transmission benefits currently allowed under the C-TPAT and/or FAST programs to food products subject to FDA's prior notice requirements.

In response to FDA's question on how this should be accomplished, BC suggests that the extension of these benefits be established for C-TPAT or FAST members/participants through the existing C-TPAT or FAST programs. Further discussion of how this should be accomplished is discussed under our response to question 3.

3. Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

BASF Corporation suggests that the importer who is subject to FDA Prior Notice requirements submit to the FDA (with a copy to CBP) the following:

a. A statement or proof of acceptance (e.g. copy of acceptance letter from CBP) into the C-TPAT and/or FAST programs;

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3000 Continental Drive - North
Mount Olive, N.J. 07828 -1234
Tel: (800) 526-1072
www.basf.com/usa

b. A detailed statement/description of policies and procedures in place for meeting FDA Prior Notice requirements. This submission should follow the format of the supply chain questionnaire information submitted to CPB as part of the C-TPAT application process and should be considered as an addendum to the original submission; and
c. FDA should notify the importer in writing of: (1) its acceptance/agreement with the importer's FDA Prior Notice procedures; or (2) additional questions to be answered or data provided to meet FDA requirements for acceptance into the FDA PN "C-TPAT/FAST" program.

BASF Corporation's Responses Regarding Flexible Alternative Questions:

1. If timeframes were reduced in FDA's prior notice final rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?

BASF Corporation believes that other flexible alternatives should be extended to participants in FAST or other agency programs.

2. In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

BASF Corporation recommends that FDA coordinate systematic solutions with Animal Plant Health Inspection Service (USDA/DHS), which also has responsibility for the importation of foodstuffs. The importer should be able to address APHIS requirements at the same time as FDA Prior Notice requirements are addressed through the ABI system. Ideally, the submission of data for both agencies (as well as CBP) should be accomplished through the International Trade Data System (ITDS), which would allow for one portal for the submission of all regulatory required data to the federal government.

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3000 Continental Drive - North
Mount Olive, N.J. 07828 -1234
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As to FDA's question regarding inspection of companies, the inspection of companies in the supply chain could occur in conjunction with CBP C-TPAT validations. BASF Corporation discusses this further under their response to FDA's question 4.

4. Are there conditions of participation that FDA should consider, e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

BASF Corporation recommends that FDA either be included in CBP C-TPAT validations or utilize the CBP C-TPAT system and approvals for FDA validation. This will result in only one validation for the importer and will result in efficiencies of scale for both the importer and the two agencies. Perhaps CBP C-TPAT officers could be trained in FDA requirements to reduce the duplication of effort and the additional number of employees required for these validations.

5. If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

Yes, BASF Corporation agrees that the shorter timeframes be phased in consistent with CBP phasing in the advanced electronic rule.

6. Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

Yes, BASF Corporation agrees that FDA should offer prior notice submission training. Such a program will help ensure uniformity and can significantly reduce errors in transmission. We suggest that FDA maintain an on-going dialogue for discussion of issues, problems and suggestions for improvements/streamlining with various parties affected and interested trade associations, such as the National Customs Brokers and Freight Forwarders Association (NCBFFA) and the American Association of Exporters and Importers (AAEI).

BASF Corporation
3000 Continental Drive - North
Mount Olive, N.J. 07828 -1234
Tel: (800) 526-1072
www.basf.com/usa

II. BASF Corporation 's Comments on FDA's Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes, Availability

BASF Corporation would like to concur with the proposed joint FDA-CBP plan for increasing integration of both activities of both agencies and in the coordination of PN timeframes with those of the Advance Electronic Presentation of Cargo Information, as this will eliminate the current requirement for importer's to maintain two differing timeframes for the provision of data for both FDA's Prior Notice System Interface (FDA PN interface) requirements and for the CBP. This proposed plan should result in economies of scale for both agencies.

III. BASF Corporation's Request for Clarification on the Definition of "Food Contact Substances" in the IFR as Including Secondary Direct Food Additives

BASF Corporation asks if what are called "secondary direct food additives" as listed in 21 CFR Part 173 considered "Food Contact Substances" as defined in Section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and therefore exempt from the IFR requirements for Prior Notice (as well as for the IFR requirements for Registration of Food Facilities set out in the *Federal Register* of October 10, 2003 (68 FR 58894) and other aspects of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the IFRs)).

The IFRs clearly exempt "food contact substances" including food packaging from the requirements of these regulations. The preamble to the IFRs are not clear on whether FDA intends to consider secondary direct food additives, many of which are food processing aids, within the definition of food contact substances for the purposes of the Bioterrorism Act, and therefore, exempt from the IFRs' requirements.

The Preamble to the Prior Notice IFR, 68 FR 58984, at 58986, says that processing aids are subject to the rule. Does FDA intend to exclude processing aids that are not intend to have a technical effect on the final food product that is consumed, but only on the processing of such food product? The preamble to the Prior Notice Interim Final Rule states "[if] a substance is not a pesticide and is intended to have a technical effect in the food being processed, the substance is not exempt from the definition of 'food' under

BASF Corporation
3000 Continental Drive - North
Mount Olive, N.J. 07828 -1234
Tel: (800) 526-1072
www.basf.com/usa

Section 1.276(b)(5) in the interim final rule. This is a reasonable result in that such processing aids are intentionally and directly added to 'traditional' foods'." The Preamble to the Registration IRF notes that "there are a wide variety of processing aids used in packaging and other food contact materials and processing aids used in 'traditional' food" and this Interim Final Rule also states that "[in] terms of processing aids, this means that generally speaking, facilities that manufacture/process, pack or hold processing aids used in the production of 'traditional' food will be required to register. This is a reasonable result in that such processing aids are intentionally and directly added to 'traditional' foods" (68 FR 58894, at 58911). These statements in the Preambles to the IFRs do not clearly indicate the status of secondary direct food additives.

Secondary direct food additives listed in Part 173 are food processing aids that was intended to have an effect on the food during manufacture/processing but are not intended to remain in the final food after processing and are not intended to affect the food as consumed (or as further processed/manufactured). Food Contact Substances are defined in Section 409(h)(6) of the FFDCA as "any substance intended for use as a component of materials used in the manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect on that food." This definition clearly excludes materials or their components that do not have a technical effect on the food as consumed.

The FDA "Guidance for Preparation of FCS: Administrative, Final Guidance, May 2002" states "FDA also recognizes that some substances that are intended to have a technical effect in food during processing (processing aids) but not after processing may be included in the definition of FCS, and thus also may be the subject of an FCN". In fact, secondary direct food additives have been accepted by FDA through a Food Contact Notification ("FCN") and therefore considered "food contact substances." For example, such a secondary direct food additive that have been the subject of FCNs are a processing / filter aid for beer and wine that is removed from the final beverage.

Not only has FDA accepted secondary direct food additives as food contact substances, but such secondary direct food additives clearly meet the criteria that FDA used to exclude food-contact materials from the Interim Final Rules requirements as they are not "food for consumption" in that "they are not intentionally eaten for their taste, aroma, or nutritive value" (68 FR 58894, at 58911).

BASF Corporation
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Furthermore, we believe secondary direct food additives pose minimal, if any, bioterrorism risk, as such components are no long in the food that is intended for consumption.

BASF Corporation requests that FDA clarify that it intends to exempt from the requirements of the IFRs all secondary direct food additives (21 CFR Part 173) because they meet the criteria for a food contact substances as defined in Section 409(h)(6) of the FFDCA. If that is not FDA's intent, we ask that FDA either: (a) define the criteria for which secondary direct food additives meet the definition of food contact substance; and therefore, are exempt from the Interim Final Rules, or (b) exempt all secondary direct food additives that have been accepted as FCNs by FDA because by such acceptance FDA has acknowledged that those secondary direct food additives meet the definition of a food contact substance.

Conclusion

In conclusion, we commend FDA and CBP on the development of these alternatives and believe both the flexibility in using these programs and the reduced timeframes will result in significant efficiencies for the agencies and submitters, while continuing to offer protection of our food supply from possible or actual terrorist attacks. BASF asks for clarification regarding the inclusion of secondary direct additives in the definition of Food Contact Substances and therefore their exclusion from the requirements of Prior Notice of Imported Food, as well as the requirements for Registration under the Bioterrorism Act. BASF respectfully requests that FDA consider these comments when issuing final rules regarding Prior Notice and other requirements of the Bioterrorism Act.

Should FDA have any additional questions regarding this submission, I can be reached at (973) 426-3898.

Sincerely,

C. Good /cle

Christina L. Good
Senior Counsel,
Product and Trade Regulation

BASF Corporation
3000 Continental Drive - North
Mount Olive, N.J. 07828 -1234
Tel: (800) 526-1072
www.basf.com/usa